DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1153B

WARNING LETTER

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

Mr. William L. Roper
Chairman
Magnetherapy, Incorporated
760 U.S. Highway 1
Suite 101
West Palm Beach, Florida 33408

FEB 3 1997

Re: Tectonic Magnets

Dear Mr. Roper:

The Food and Drug Administration (FDA) has reviewed promotional materials for Tectonic Magnets. Tectonic magnets are manufactured by Magnetherapy, Incorporated and are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your promotional piece titled, "Natural Pain Relief with New Tectonic Magnets," which appeared in the February 2, 1997 issue of Parade Magazine, makes medical statements that clearly imply that Tectonic Magnets can relieve a variety of disease states and conditions in the body, and that therefore cause these devices to require either premarket clearance through the 510(k) process, or an approved premarketing application through the PMA process pursuant to sections 510(k) and 515 of the Act, respectively (see below). Under the provisions of section 201(h) of the Act, any product which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or which is intended to affect the structure or any function of the body of man, and which does not achieve its primary intended purposes through chemical action within or on the body of man, and which is not dependent upon being metabolized for the achievement of its primary intended purposes, is a device within the meaning of this section of the Act.

Your piece promotes Tectonic Magnets for a variety of medical claims including: relief of arthritis, tennis elbow, lower back pain, sciatica, migraine headaches, muscle soreness, neck, knee, ankle, and shoulder pain, heel spurs, bunions, arthritic fingers, toes, and to reduce pain and inflammation in the affected area by increasing blood and oxygen flow.

Additionally, we have also reviewed Magnetherapy, Incorporated's home page on the Internet at the web address: http://www.pbol.com/magnetherapy. The Agency has determined that materials appearing on the Internet are subject to the same regulations as materials distributed by other means. Your home page makes similar claims for the relief of the above medical conditions. Although both the Parade advertisement and the promotional materials appearing on your home page contain disclaimers stating that "Tectonic Magnets are not being sold as medical devices," and that the products are not designed or intended to cure painful conditions, these products are in fact devices, as defined under the Act, and as such do require either an approved PMA or a cleared 510(k) prior to marketing.

Tectonic Magnets are adulterated within the meaning of section 501(f)(1)(B) of the Act in that these claims elevate the device to Class III status under section 513(f) and do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

Tectonic Magnets are misbranded under section 502(o) of the Act in that the

device was manufactured, prepared, propagated, compounded or processed in an establishment not duly registered under section 510(k), was not included in a list required by section 510(j), and a notice or other information respecting the device was not provided to FDA as required by section 510(k), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your devices. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter also may be reflected in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing all materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. The continued sale or distribution of Tectonic Magnet products may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should also include steps being taken tc address any misleading information currently in the market place and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to the FDA District Office. Please send a copy of your response to the District Director, Florida District Office, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health